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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,466	03/09/2001	Paul D. Taylor	P-408	7041

7590 06/03/2003
Keith Johnson, Esq.
Transgenomic, Inc.
12325 Emmett Street
Omaha, NE 68164

EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,466

Applicant(s)

TAYLOR ET AL.

Examiner.

Maria B Marvich, PhD

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-- Th MAILING DATE of this communication appears on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 12, 21, 23, 26, 27 and 30-33 is/are rejected.
- 7) ☒ Claim(s) 5, 7-10, 12-20, 22-25, 28, 29 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a response to a restriction requirement filed 3/24/03.

Election/Restrictions

Applicant's election without traverse of the species: silica separation medium, triethylammonium acetate counterion agent and acetonitrile mobile phase in Paper No. 8 is acknowledged. The remaining species are withdrawn from consideration. Claims 13-19, 20, 22, 24, 25 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Information Disclosure Statement

The Information Disclosure Statement is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code as the information in the IDS is printed on the face of the file, the embedded hyperlink and or other browser executable codes must be deleted. See MPEP § 608.01.

The Information Disclosure Statement contains three patent applications by others. The applications have been considered but have been crossed through on the IDS and will not be published on the face of the file because there is a valid reason (35 USC 122) why the office would not want certain pending applications be listed as prior art on the face of the patent.

Specification

The disclosure is objected to because of the following informalities: on page 23, line 24, figure 14 appears to be mistakenly referred to as figure 4. Acetonitrile on page 30, line 25 is misspelled. Appropriate correction is required.

Claim Objections

Claim 5 is objected to because of the following informalities: MIPC is abbreviated, the term should be spelled out completely for clarity. Appropriate correction is required.

Claim 32 is objected to because of the following informalities: A space is required between “inhibitors” and “and”. Appropriate correction is required.

Summary of the invention

The invention recites a method for stabilizing an RNA molecule against degradation in which the stability is increased due to “elution is conducted under conditions that result in a substantial separation of the RNA molecule from the agent capable of catalyzing the degradation of RNA”. It is explained in the specification that it is a surprising discovery that RNA molecules that have been eluted from the column are remarkably stable (page 28, line 19-26). Absent evidence to the contrary, no special elution steps are provided. Rather, RNase is eluted at the beginning of the gradient under initial conditions in which the RNA molecules remain retained in the column (page 31, line 10-19). The stability of RNA following elution is illustrated in examples 10-13. For purposes of identifying prior art, conditions that are depicted in example 10 and 11 are assumed to be adequate to perform the instant invention. In example 11, a mouse brain mRNA

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sample was separated by MIPC on a DNASep chromatography cartridge of which the stationary phase of the cartridge comprises non-porous, C-18 alkylated poly(styrene-divinylbenzene) separation medium although silica is the elected separation medium. Chromatography was performed using 0.1 M triethylammonium acetate (TEAA) pH 7.0 and TEAA with 25% acetonitrile. Separation was performed under fully denaturing conditions at 75°C.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 11, 12, 21, 23, 26, 27, 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gjerde WO 98/56798 (filed December 17, 1998) provided by applicant.

Gjerde et al teach separation of polynucleotides by MIPC wherein multivalent cations are removed from all aspects (page 3, line 17-19). The separation media can be silica and support non-polar organic polymers or long chain C1 to C24 hydrocarbon groups bound to inorganic substrate (page 5, line 1- 17). The separation media has an average diameter of 1-100 microns (page 3, line 23). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (page 9, line 21) and the procedure can be used for batch process (page 5, line 18-25). The method comprises contacting the separation media with

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eluting solution A, which consists of 0.1 M TEAA pH 7.2 and B, which consists of 0.1 M TEAA and 25% acetonitrile (page 32, line 20-22). The procedure disclosed by Gjerde et al. is the same as that recited in the instant invention and would be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA.

Claims 1-6, 11, 12, 21, 23, 26, 27, 30-33 are rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Gjerde US 5,972, 222 (filed May 18, 1998 and published October 26, 1999) provided by applicant.

Gjerde et al teach separation of polynucleotides by MIPC (column 3, line 15-17) multivalent cations are removed from all aspects (column 2, line 43-45). The separation media can be silica and support non-polar organic polymers or long chain C1 to C24 hydrocarbon groups bound to inorganic substrate (column 2, line 63 to column 3, line 2 and column 16, line 40). The separation media has an average diameter of 1-100 microns (column 2, line 31). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (column 5, line 11-20) and the procedure can be used for batch processes (column 3, line 22). The method comprises contacting the separation media with eluting solution A consists of 0.1 M TEAA pH 7.2 and B which consists of 0.1 M TEAA and 25% acetonitrile (column 14, line 45-67 and column 15, line 65 to column 16 line 10). The procedure disclosed by Gjerde et al. is the same as that recited in the instant invention and would be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA.

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Claims 1-6, 11, 12, 21, 23, 26, 27, 30-33 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Gjerde et al US 5,986,085 (filing date April 24, 1998 and publication date November 16, 1999) provided by applicant.

Gjerde et al teach a batch process for obtaining polynucleotides from a mixture of polynucleotide fragments (abstract) such as RNA (column 3, line 24-36). A counterion such as TEAA is preferred (column 3, line 37-43). Multivalent cations are removed from all aspects (column 2, line 43-45). The separation media can be silica and support non-polar organic polymers or long chain C8 to C24 hydrocarbon groups bound to inorganic substrate (column 5, line 48- 62). The separation media has an average diameter of 1-100 microns (column 6, line 2). The present invention can be used in the separation of RNA although for purposes of description, DNA is described (column 5, line 11-20) and the procedure can be used for batch process (column 3, line 22). The method comprises of contacting the beads and polynucleotides with and then contacting the separation media with eluting solution such as 0.1 M TEAA pH 7.2 and a gradient of 33%-55% acetonitrile (column 10, line 65-67). The procedure disclosed by Gjerde et al. is the same as that recited in the instant invention and would be expected to yield RNA that is substantially free of agents capable of catalyzing degradation of RNA.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the nuclease" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 12-20, 22-25 and 29 are objected to in as much as they are drawn to non-elected subject matter. Claims 5 and 32 are objected to because of minor informalities.

Claims 1-6, 11, 12, 21, 23, 26, 27, 30-33 are rejected.

Claims 7-10 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
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June 2, 2003

DAVID GUZO
PRIMARY EXAMINER
